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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/004,606	01/08/98	STICE	S 000270-018

021839 HM22/0301
BURNS DOANE SWECKER & MATHIS
P O BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER	
CROUCH, D	
ART UNIT	**PAPER NUMBER**
1632	16

DATE MAILED: 03/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/004,606	Stice et al.
Examiner	**Group Art Unit**
Deborah Crouch	1632

☒ Responsive to communication(s) filed on *Jan 10, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three (3)* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *86-109* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *86-109* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicant's arguments filed January 10, 2000 in paper no. 15 have been fully considered but they are not persuasive. The amendment canceled claims 1-85 and inserted claims 86-109 has been entered. The declaration by James M. Robl, Ph.D. has been considered but is not deemed fully persuasive.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 86-109 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,945,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious over the claims of '752. The instant claims are improved methods of cloning a non-human mammal by nuclear transfer using as the donor a proliferating somatic cell or a proliferating somatic cell nucleus. The claims of '577 are to improved methods of cloning non-human mammals by nuclear transfer using as the donor somatic cell or donor somatic cell nucleus a proliferating somatic cell or a nucleus of a proliferating somatic cell, where the proliferating cell has been expanded in vitro. Thus the instant claims are obvious over the claims of '577 as expansion in culture is one of many ways that a cell proliferates. Thus at the instant claims would have been obvious to the ordinary artisan at the time of filing.

These are provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant request that this rejection be held in abeyance until allowable subject mater is indicated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an improved method of cloning by nuclear transfer using as the donor cell or donor cell nucleus a proliferating somatic cell which has been expanded in culture, does not reasonably provide enablement for an improved method of cloning using as the donor cell or donor cell nucleus any proliferating cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enablement rejection centers on what is a "proliferating somatic cell"? It can be argued that all cell proliferate, even if some only proliferate under certain conditions. For example, muscle or liver cells do not proliferate unless injured or diseased. For the most part muscle cells and liver cells are considered to be terminally differentiated and are out of the growth phase. The specification does not describe or contemplate the use of such terminally differentiated cells directly in a cloning procedure. The only clear contemplation of donor cell treatment comes from the working examples, and that is to grow the fibroblast cells in culture and then select from the expanded population a cell to use as the donor in cloning procedures (specification, pages 49-50, bridg. parag. and page 61, parag. 1). It is noted that the art as whole teaches that the donor cell, when cloning using non-embryonic or somatic cells, some

out-side event or external stimulus or condition needs to be applied to the cells for the nucleus to reprogram itself or re-model the genome such that it becomes totipotent. Fulka et al state that the success when embryonic cells were used as donor was likely due to the embryo cells not being completely differentiated at the time of transfer, and thus amenable to undergo full reprogramming (page 848, col. 1, parag. 1, line 1 to col. 2, line 1). Kono states that a break down of the nuclear envelop is necessary for reprogramming, as reprogramming probably requires the contact of the chromatin with the ooplasm (page 76, col. 2, parag. 2, lines 1-6). Thus, critical to cloning of non-human mammals from somatic cell nuclei is the reprogramming effect. The specification does not point out any special treatment or feature of the disclosed protocol which is responsible for the reprogramming step. The only discernable treatment is that of selecting as donor a cell from an expanded culture. Thus the claims are so limited because the specification fails to provide guidance as to situations which induce reprogramming or nuclear remodeling. At the time of the instant invention the artisan would have needed to engage in an undue amount of experimentation to implement the invention as claimed. It is noted that Fulka et al stated that the cloning of adult mammals is very inefficient and highly unpredictable (page 849, col. 1, lines 9-10 and page 850-851, bridg. sent.).

Applicant argues that a copy of the declaration by James M. Robl, Ph.D. made in 07/781,752, should overcome the rejections made in the previous office action. Applicant argues that in the Robl declaration, the use of proliferating cells from adult mammals has been reported. These arguments are not fully persuasive.

The Robl declaration is persuasive for the scope rejection given. However, the declaration does not provide sufficient detail on post-filing evidence and/or publications that one can readily determine how the donor cells in these evidence and/or publications were treated prior to use in the cloning method. Further, there needs to be a direct correlation between the methods disclosed in the specification and those in the post-filing evidence and/or publications.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 109 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 109 is a duplicate of claim 108. As an applicant can have only one claim to any invention, claim 109 should be canceled or re-written.

Applicant's amendments has overcome the rejections made under 35 U.S.C. 112, first and second paragraphs, 35 U.S.C. 102 and 35 U.S.C. 103 made in the previous office action.

Claims 86-109 are free of the prior art. At the time of filing the art did not teach or suggest the cloning of non-human mammals by nuclear transfer using as a donor a proliferating somatic cell or a nucleus from a proliferating somatic cell, where the somatic cell had been expanded in culture.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

The fax number is (703) 308-4242.

Deborah D Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Dr. D. Crouch
February 26, 2000